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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,384	10/22/2003	Stephen P. Oliver	HME/7477.0017	8786

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EXAMINER	
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ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/691,384	OLIVER ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/22/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Request for Continued Examination

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed on 10/09/07 has been entered.

Applicants' Amendments

2) Acknowledgment is made of Applicants' amendments filed 01/15/08 and 10/09/07 in response to the final Office Action mailed 07/17/07.

Status of Claims

3) Claims 1 and 2 have been amended via the amendment filed 10/09/07.

New claim 48 has been added via the amendment filed 10/09/07.

Claims 1, 2, 15-17, 36-39 and 46-48 are pending.

Claims 1, 2 and 48 are under examination.

Rejection(s) Withdrawn

4) The rejection of claims 1 and 2 made in paragraph 13 of the Office Action mailed 03/08/07 and maintained in paragraph 20 of the Office Action 07/17/07 under 35 U.S.C § 102(b) as being anticipated by Park *et al.* (*In: Proceedings of the 40th Annual Meeting of National Mastitis Council*, National Council Incorporated, pages 247-248, February 2001), is withdrawn in light of Applicants' amendment to the claims.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

5) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

6) Claim 48 is rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 48 is indefinite and confusing in the limitation: 'having an amino acid sequence consisting of'. The transitional limitation 'having' similar to the term 'including', 'containing', or 'characterized by' represents open-ended claim language and therefore does not exclude additional unrecited elements. See M.P.E.P 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986)*; *In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981)*; *Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948)* ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts'). On the other hand, the limitation 'consisting of' represents closed claim language and excludes any element, step, or ingredient not specified in the claim. *In re Gray, 53 F.2d 520, 11 USPQ 255 (CCPA 1931)*; *Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948)*. It is unclear from the phrase 'having an amino acid sequence consisting of' whether Applicants intend open claim language or closed claim language.

Rejection(s) under 35 U.S.C. § 103

7) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a)** A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

8) Claims 1, 2 and 48 are rejected under 35 U.S.C § 103(a) as being unpatentable over Park *et al.* (*In: Proceedings of the 40th Annual Meeting of National Mastitis Council*, National Council Incorporated, pages 247-248, February 2001, already of

record) or Fang *et al.* (*FEMS Microbiol. Lett.* 176: 91-96, 1999 – Applicants' IDS) in view of Hammerschmidt *et al.* (*Infect. Immun.* 67: 1683-1687, April, 1999) or Staggs *et al.* (*Mol. Microbiol.* 12: 613-619, 1994) or Biswas *et al.* (*Infect. Immun.* 67: 455-459, January 1999).

The limitation 'consisting essentially of' in claim 2 and the indefinite limitation 'having an amino acid sequence consisting of' in claim 48 are interpreted in this rejection as being equivalent to 'comprising'.

Park *et al.* taught an isolated 110 or 112 kDa lactoferrin-binding protein (i.e., polypeptide) from ATCC 13387, UT888, UT366, or UT102 strain of *Streptococcus uberis*. Park *et al.* expressly suggested the purification and subsequent characterization of their lactoferrin-binding protein. See pages 247 and 248. The polypeptide was obtained by an SDS extraction method that is identical to the method described in Example 4 of the instant specification for obtaining the 110 kDa or 112 kDa protein of the instant invention that contains the amino acid sequence of SEQ ID NO: 4, i.e., MTTADQSPKLQGEEA, as described in Example 7 of the instant specification. Although Park *et al.* are silent about the amino acid composition of the N-terminal sequence of their *Streptococcus uberis* 112 or 110 kDa protein or polypeptide, the amino acid sequence as recited is viewed as an inherent feature of Park's isolated *Streptococcus uberis* 112 or 110 kDa polypeptide which was already known in the prior art. Because of the overlapping molecular weight, the *Streptococcus uberis* origin of the prior art polypeptide, the identical *Streptococcus uberis* ATCC13387 strain from which it was extracted by the identical SDS extraction method, the prior art polypeptide is viewed as the same as the isolated polypeptide claimed in the instant claims, and therefore it is expected to have the same intrinsic structure and properties as that of the Applicants' polypeptide. The Office's position that the prior art polypeptide is the same as Applicants' polypeptide is based upon the fact that every characteristic overlapping in the prior art polypeptide and the Applicants' polypeptide are the same.

Fang *et al.* taught an isolated 112 kDa lactoferrin-binding protein (i.e., polypeptide) from ATCC 13387, UT888, UT366, or UT102 strain of *Streptococcus uberis*. The polypeptide was obtained by an SDS extraction method that is identical to

the method described in Example 4 of the instant specification for obtaining the 112 kDa protein of the instant invention that contains the amino acid sequence of SEQ ID NO: 4, i.e., MTTADQSPKLQGEEA, as described in Example 7 of the instant specification. See section 2.7; Figure 3; top panel of Figure 1; and page 95. Although Fang *et al.* are silent about the amino acid composition of the N-terminal sequence of their *Streptococcus uberis* 112 kDa protein or polypeptide, the amino acid sequence as recited is viewed as an inherent feature of Fang's isolated *Streptococcus uberis* 112 kDa polypeptide which was already known in the prior art. Because of the overlapping molecular weight and the *Streptococcus uberis* origin of the prior art polypeptide, and the identical *Streptococcus uberis* ATCC13387 strain from which it was extracted by the identical SDS extraction method, the prior art polypeptide is viewed as the same as the isolated form of the polypeptide claimed in the instant claims.

Park *et al.* or Fang *et al.* do not expressly teach that their isolated polypeptide is purified.

However, methods of purifying an art-known lactoferrin-binding protein or polypeptide were well known, conventional, and routinely practiced in the art at the time of the invention. For instance, Hammerschmidt *et al.* taught a method of use of lactoferrin affinity chromatography to purify a streptococcal lactoferrin-binding bacterial protein. See paragraph bridging pages 1683 and 1684.

Similarly, Staggs *et al.* taught the use of lactoferrin affinity chromatography to purify a bacterial lactoferrin-binding protein. See Figure 1; right column of page 614; and 'Experimental procedures'.

Likewise, Biswas *et al.* taught the routine lactoferrin-agarose affinity purification of a lactoferrin-binding bacterial protein. See page 458.

Given that it was routine and conventional in the art to purify an art-known bacterial or streptococcal lactoferrin-binding protein using a method that uses the art-known lactoferrin affinity chromatography as taught Hammerschmidt *et al.*, Staggs *et al.* or Biswas *et al.*, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to purify Parks' or Fang's *Streptococcus uberis* lactoferrin-binding protein or polypeptide using Hammerschmidt's, Staggs', or Biswas's

lactoferrin affinity chromatography to produce the purified polypeptide of the instant invention with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of providing Parks' or Fang's *Streptococcus uberis* lactoferrin-binding protein or polypeptide in a purified form for the purpose of subsequent characterization of their lactoferrin-binding protein as expressly taught by Park *et al.*

Claims 1, 2 and 48 are *prima facie* obvious over the prior art of record.

Remarks

9) Claims 1, 2 and 48 stand rejected. The deletion of the phrase 'having an amino acid sequence' from claim 48 would obviate the art rejection of record.

10) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted to the Office' Central Rightfax number 571-273-8300 via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week.

11) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

12) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Shanon Foley, can be reached on (571) 272-0898.

/S. Devi/
S. Devi, Ph.D.
Primary Examiner
AU 1645

April, 2008